



Docket No.: 4686-121.2

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Diane Dunn McKay

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	:
SHEFER et al..	:
Serial No.: 10/791,989	: Group Art Unit: TBD
Filed: March 3, 2004	: Examiner: TBD
Title ORAL CONTROLLED RELEASE SYSTEM FOR TARGETED DRUG DELIVERY INTO THE CELL AND ITS NUCLEUS FOR GENE THERAPY, DNA VACCINATION, AND ADMINISTRATION OF GENE BASED DRUGS	: : : : : : x

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

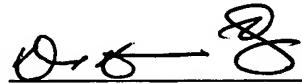
Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, Applicant hereby brings to the attention of the United States Patent and Trademark Office the following documents of which Applicant has been made aware. The documents are listed on the attached PTO Form 1449. Copies of the documents are enclosed.

Applicant submits that this Information Disclosure Statement is submitted prior to a first action on the merits.

It is requested that the references be considered by the Examiner and be made of record as part of the available prior art under 37 C.F.R. § 1.104.

Respectfully submitted,



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INFORMATION DISCLOSURE CITATION <i>(Use several sheets if necessary)</i>			Docket Number (Optional) 4686-121.2 US		Application Number 10/791,989			
			Applicant(s) SHEFER et al.					
			Filing Date March 3, 2004		Group Art Unit TBD			
			U.S. PATENT DOCUMENTS					
*EXAMINER INITIAL	REF	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
		3,686,025	08/22/1972	MORTON	117	140		
		3,689,435	09/05/1972	BERNI et al.	252	524		
		4,096,238	06/20/1978	ZAFFARONI et al.	424	15		
		4,145,184	03/20/1979	BRAIN et al.	8	137		
		4,152,272	05/01/1979	YOUNG	510	101		
		4,250,043	02/10/1981	JONES	510	327		
		4,402,856	09/06/1983	SCHNORING et al.	428	402.22		
		4,434,086	02/28/1984	HILL et al.	428	221		
		4,446,032	05/01/1984	MUNTEANU et al.	510	515		
		4,464,271	08/07/1984	MUNTEANU et al.	510	515		
		4,476,041	10/09/1984	HILL et al.	510	101		
FOREIGN PATENT DOCUMENTS								
	REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
							YES	NO
		0 334 490 B1	02/23/1989	European				
		0 376 385	12/20/1989	European				
		EP 0 469 228 B1	07/31/1990	European				
		0 539 025 A2	09/22/1992	European				
		EP 0 764 717 A1	09/18/1996	European				
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)								
		Prescott, D et al., The Relationship Between Intracellular and Extracellular pH in Spontaneous Canine Tumors, Clinical Cancer Research, Vol. 6, 2501-2505, June 2000;						
		Sawhney, A et al., Bioerodible Hydrogels Based on Photopolymerized Poly(ethylene glycol)-co-poly(alpha-hydroxy acid)Diacylate Macromers, Macromolecules 1993, 26, 581-587;						
EXAMINER				DATE CONSIDERED				
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.								

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		4,488,973	12/18/1984	HILL et al.	424	69	
		4,503,030	03/05/1985	EDGREN et al.	424	473	
		4,517,359	05/14/1985	KOBREHEL et al.	536	7.4	
		4,522,625	06/11/1985	EDGREN	424	473	
		4,536,315	08/20/1985	RAMACHANDRAN et al.	510	349	
		4,578,075	03/25/1986	URQUHART et al.	604	892	
		4,587,117	05/06/1986	EDGREN et al.	424	15	
		4,636,330	01/13/1987	MELVILLE	08	137	
		4,681,583	07/21/1987	URQUHART et al.	604	892	
		4,842,761	06/27/1989	RUTHERFORD	510	297	
		4,851,231	07/25/1989	URQUHART et al.	424	469	

FOREIGN PATENT DOCUMENTS

	REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
							YES	NO
		EP 0 908 174 A2	08/18/1998	European				
		EP 0 925 776 A2	12/10/1998	European				
		WO 93 05136	03/18/1992	PCT				
		WO 93 05137	03/18/1993	PCT				
		WO 93 05139	03/18/1993	PCT				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Wani, M.C et al., Plant Antitumor Agents. VI. The Isolation and Structure of Taxol, a Novel Antileukemic and Antitumor Agent from <i>Taxus Brevifolia</i> , <i>Journal of the American Chemical Society</i> , 93:9, May 5, 1971;
	Balassa, L et al., Microencapsulatoin in the Food Industry, <i>CRC Critical Reviews in Food Technology</i> , July 1971, pp. 245-265;

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		4,910,021	03/20/1990	DAVIS et al.	424	456	
		4,919,841	04/24/1990	KAMEL et al.	252	186.26	
		4,946,624	08/07/1990	MICHAEL	510	101	
		4,954,285	09/04/1990	WIERENGA et al.	510	101	
		5,051,222	09/24/1991	MARTEN et al.	264	143	
		5,066,419	11/19/1991	WALLEY et al.	510	396	
		5,094,761	03/10/1992	TRINH et al.	510	515	
		5,102,564	04/07/1992	GARDLIK et al.	427	394	
		5,112,688	05/12/1992	MICHAEL	428	402.2	
		5,137,646	08/11/1992	SCHMIDT et al.	510	515	
		5,175,003	12/29/1992	GOLDMAN	424	484	

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	REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
							YES	NO
		WO 93 13195	07/08/1993	PCT				
		WO 94 19448	09/01/1994	PCT				
		WO 94 27107	11/24/1994	PCT				
		WO 97 11152	03/27/1997	PCT				
		WO 97 34981	09/25/1997	PCT				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Lehr, C et al., The potential of Bioadhesive Lectins for the Delivery of Peptide and Protein Drugs to the Gastrointestinal Tract, <i>Lectins: Biomedical Perspectives</i> , pp. 117-139;
	Duchene, D et al., Pharmaceutical and Medical Aspects of Bioadhesive Systems for Drug Administration, <i>Drug Development and Industrial Pharmacy</i> , 14 (2&3), 283-318 (1988);

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		5,188,753	02/23/1993	SCHMIDT et al.	510	395	
		5,207,933	05/04/1993	TRINH et al.	510	517	
		5,232,612	08/03/1993	TRINH et al.	510	515	
		5,232,613	08/03/1993	BACON et al.	510	101	
		5,234,610	08/10/1993	GARDLIK et al.	510	327	
		5,234,611	08/10/1993	TRINH et al.	510	523	
		5,236,615	08/17/1993	TRINH et al.	510	349	
		5,246,603	09/21/1993	TSAUR et al.	510	519	
		5,281,355	01/25/1994	TSAUR et al.	510	393	
		5,288,423	02/22/1994	BEHAN et al.	510	119	
		5,316,774	05/31/1994	EURY et al.	424	501	

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						YES	NO
	WO 97 47720	12/18/1997	PCT				
	WO 98 12298	03/26/1998	PCT				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

Gerweck, L et al., Cellular pH Gradient in Tumor versus Normal Tissue: Potential Exploitation for the Treatment of Cancer, Cancer Research 56, 1194-1198, March 15, 1996.

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		5,324,444	06/28/1994	BERRY et al.	512	4	
		5,358,502	10/25/1994	HERBIG et al.	604	892.1	
		5,385,959	01/31/1995	TSAUR et al.	501	530	
		5,425,887	06/20/1995	LAM et al.	510	520	
		5,417,153	05/23/1995	KING et al.	99	517	
		5,484,610	01/16/1996	BAE	424	487	
		5,508,259	04/16/1996	HOLZNER et al.	512	4	
		5,525,367	06/11/1996	KING et al.	99	517	
		5,554,147	09/10/1996	BATICH et al.	604	890.1	
		5,562,847	10/08/1996	WAITE et al.	510	519	
		5,609,590	3/11/1997	HERBIG et al.	604	892.1	

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		5,656,292	08/12/1997	URTTI et al.	424	464	
		5,656,584	08/12/1997	ANGELL et al.	510	441	
		5,668,097	09/16/1997	TRINH et al.	510	293	
		5,691,303.	11/25/1997	PAN et al.	512	4	
		5,788,687	08/04/1998	BATICH et al.	604	890.1	
		5,814,592	09/29/1998	KAHN et al.	510	304	
		5,840,668	11/24/1998	BEHAN et al.	510	112	
		5,858,959	01/12/1999	SURUTZIDIS et al.	510	507	
		5,955,419	09/21/1999	BARKET Jr et al.	510	507	
		6,025,319	02/15/2000	SURUTZIDIS et al.	510	441	
		6,042,792	03/28/2000	SHEFER et al.	422	259	

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SHEFER et al.

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Group Art Unit

TBD

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		6,048,830	04/11/2000	GALLON et al.	510	349	
		6,051,540	04/18/2000	SHEFER et al.	510	101	
		6,068,859	05/30/2000	CURATOLO et al.	510	515	
		6,093,691	07/25/2000	SIVIK et al.	510	515	
		6,103,865	08/15/2000	BAE et al.	258	373	
		6,228,396	05/08/2001	WATTS	424	463	
		6,306,422	10/23/2001	BATICH et al.	424	423	
		6,365,187 B2	04/02/2002	MATHIOWITZ et al.	424	486	
		6,383,811	05/07/2002	WOLFF et al.	435	450	
		6,426,086 B1	07/30/2002	PAPAHADJOPoulos et al.	424	450	
		6,475,995	11/05/2002	ROY et al.	514	44	

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		6,602,524 B2	08/05/2003	BATICH et al.	424	489		
		6,652,884	11/25/2003	FALCIANI	424	489		
		6,664,288	12/16/2003	PARDEE et al.	514	449		
		6,669,958	12/30/2003	TRAGER et al.	424	484		
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